

REMARKS

Claims 29-52 currently appear in this application. The Office Action of July 11, 2003, has been carefully studied. These claims define novel and unobvious subject matter under Sections 102 and 103 of 35 U.S.C., and therefore should be allowed. Applicants respectfully request favorable reconsideration, entry of the present amendment, and formal allowance of the claims.

Claims 29-31 are rejected under 35 U.S.C. 102(b) as being anticipated by any of the cited Holmes-Farley et al. patents, the Examiner relying on U.S. 6,083,495 of the three substantially identical specifications.

This rejection is respectfully traversed. The claims have been amended to recite that the phosphate polymer used is particles, and the claims include the limitation of the true specific gravity of the polymer particles. Support for this amendment can be found in the specification as filed at page 23, last line through page 3, line 16, wherein the phosphate-binding polymer is described as particles.

Submitted herewith is the declaration of one of the inventors of the present application, Katsuya MATSUDA, in which he describes in detail the conditions for preparing the phosphate-binding polymer particles of the present invention, including the amounts of the polymer, solvents, and the

crosslinking agent used. The description includes detailed explanation of methods for preparing the phosphate-binding polymer particles using water alone or a mixture of water and acetonitrile as the reaction solvents. It is demonstrated in the MATSUDA declaration that these methods can sufficiently prepare polymer particles having a different specific gravity based solely on the solvent mixture used.

True specific gravity, or true density, is a commonly used parameter for identifying a characteristic of powdery or particulate solid materials. Particularly, a true specific gravity of polymers represents their physical structure such as a crystalline structure, molecular structure, and the like. True specific gravity is measured to identify not only phosphate-binding polymers, but also crystalline cellulose, halogen-containing porous synthetic resins, and some chemical compounds such as Flurbiprofen. Generally, polymer particles that have the same chemical structure as, but different true specific gravity from, other polymer particles exhibit different physical properties. Therefore, when the polymer particles are formed into tablets, the properties of the tablets differ from one another. Consequently, solid particles or powder that have a true specific gravity different from other solid particles or

powder, even of the same chemical formula, have different physical properties.

As stated in the specification, as well as in the declaration submitted herewith, the phosphate-binding polymer particles of the present invention having a true specific gravity of from 1.20-1.22 can be prepared only by crosslinking polyallylamine with epichlorohydrin in a solvent consisting of a mixture of water and acetonitrile. If the solvent used for crosslinking is water alone, as in the Holmes-Farley et al. patents, the resulting polymer particles have a true density of at least 1.25, even though the chemical structure is the same as the polymer of the present invention.

As the Examiner noted, the values of true specific gravity indicated by one of the inventors in the declaration submitted April 4, 2003, actually range from 1.2044 to 1.2174. However, if these values are rounded to three significant figures, they can be expressed as a range of from 1.20 to 1.22.. These figures support the amended claims in which the true specific gravity is expressed to three significant figures.

As is clearly indicated in the specification as filed, particularly in the Working Examples, and in the declaration submitted herewith, the phosphate-binding polymers having a true specific gravity of from 1.20 to 1.22 prepared

according to the present invention exhibit excellent properties as polymer particles to be formulated into tablets.

As shown in the declaration submitted herewith, beginning on page 6, last paragraph, the polymer particles prepared by the method of the instant invention and by the method of Holmes-Farley et al. were compressed into tablets. The polymer particles of the present invention provided tablets having a hardness of 23.9 KP, 24.3 KP and 15.5 KP, respectively. Tablets prepared by the Holmes-Farley et al. method had a hardness of 5.0 KP. Tablets having a hardness of 5 KP exhibited a considerable weight loss on the surface thereof at the beginning stage of a coating step, thereby producing a rough surface on the coated tablet. In contrast there, tablets having a hardness of 16.7 KO provided coated tablets with a smooth surface.

Accordingly, it is clear that the polymer particles of the present invention, which have a different true specific gravity from the polymer particles of Holmes-Farley et al., produce tablets having superior physical properties, particularly when the tablets are coated.

Claims 29-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over any of the Holmes-Farley et al. patents discussed above, and in view of the Examiner's comments. The Examiner notes that applicant himself has

acknowledged that the polymers of Holmes-Farley et al. and the polymers of the present invention are the same. Claims 36, 49, and 52 are product by process claims, which the Examiner alleges provide no patentable distinction to the product if the product is the same or obvious from a product of the prior art.

This rejection is respectfully traversed. As demonstrated above, even though the polymer particles of the present invention have the same chemical formula as those of Holmes-Farley et al., the particles of the polymer have different physical properties as a result of the differences in their true specific gravities. These unexpectedly different physical properties of the polymer particles of the present invention make them superior to the polymers of Holmes-Farley et al. in formulating tablets, particularly coated tablets, because of their increased hardness and lack of weight loss during coating.

As described in the declaration, the method of preparing the polymer particles of the present invention differs from the method of Holmes-Farley et al. in the solvent used. It is this element of the process that produces the unexpectedly superior particles of the present invention. While applicants concede that if the product in the product-by-process claim is the same or obvious from a product of the

prior art, the claim is unpatentable. However, in the instant case, the product produced by the process of the present invention differs from that of the prior art, and, therefore, the product is patentable.

While Holmes-Farley et al. disclose making a tablet by mixing the polymer particles with a carrier, the polymer particles of Holmes-Farley et al. are not the same as the polymer particles of the present invention. Therefore, claims to the polymer particles of the present invention are patentable over the cited Holmes-Farley et al. patents.

In view of the above, it is respectfully submitted that the claims are now in condition for allowance, and favorable action thereon is earnestly solicited.

Respectfully submitted,

BROWDY AND NEIMARK, P.L.L.C.
Attorneys for Applicant

By



Anne M. Kornbau

Registration No. 25,884

AMK:zv

Telephone No.: (202) 628-5197

Facsimile No.: (202) 737-3528

G:\BN\Y\YUAS\Matsuda 13\PTO\Amd20Nov03.doc